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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,315

03/17/2004

Jenny Voit

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08/24/2005

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EXAMINER

SHECHTMAN, SEAN P

ART UNIT

PAPER NUMBER

2125

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/802,315

Applicant(s)

VOIT ET AL.

Examiner

Sean P. Shechtman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 15-17 and 25-27 is/are rejected.
- 7) ☒ Claim(s) 4-14 and 18-24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/26/04</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1-27 are presented for examination.

#### ***Specification***

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because referring to line 16, the examiner respectfully submits that (Fig. 4) should be deleted. Correction is required. See MPEP § 608.01(b).

#### ***Claim Objections***

4. Claims 4, 5, 7, 10-14, and 18-24 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits. Claims 6, 8, and 9 inherit the deficiencies of claim 4, and therefore are also objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3, 15-17, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the patient's spine" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 2 recites the limitation "the back" in line 12. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the input" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the patient's data" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 27 recites the limitation "the patients bone" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-3, 15-17, and 25-27 are rejected under 35 U.S.C. 101 because the claims recite methods for inputting data and making determinations from the data. However, the claims describe the methods as an abstract idea in that the methods claimed can be implemented with paper files, without need for physical computing equipment and therefore constitute non-

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statutory subject matter. Examiner suggests the use of “computer implemented method” in place of “method” in order to make these claims describe statutory subject matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,741,215 to D’Urso.

Referring to claim 25, D’Urso teaches inputting patient data (Col. 7, lines 19-23), and calculating an orthosis *or* prosthesis model for the patient on the basis of said patient data (Col. 10, lines 55-67; Col. 11, line 2).

Referring to claim 26, D’Urso teaches the step of calculating comprises interpolating between different orthosis or prosthesis models (Col. 7, lines 28-33).

Referring to claim 26, D’Urso teaches the patient data of which are known (Col. 7, lines 19-23).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-3, 15-17, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,946,370 to Adler et al (hereinafter referred to as Adler) in view of U.S. Pat. No. 6,463,351 to Clynch (supplied by applicant).

Referring to claims 1, 15, and 25, Adler teaches a method and device for producing an model applicable to the study of bones for a patient comprising:

a data input for inputting patient data (Fig. 1, element 105),

determining a curvature type of the patient's spine, to be selected from a predefined number of curvature types in a database, on the basis of patient's data; selecting a model applicable to the study of bones from a predefined number of models applicable to the study of bones from the database on the basis of the determined curvature type (Col. 7, lines 45 – Col. 8, line 7).

Referring to claims 2, Adler teaches the patient's data contain *one or more* elements from the group of: radiographs, photographs of the back, static body dimensions, dynamic body dimensions and age of the patient (Col. 4, lines 20-44).

Referring to claims 3 and 17, Adler teaches at least two models are selected, further comprising: selecting a model from the at least two models in dependence on the patient's data (Col. 7, lines 45 – Col. 8, line 7).

Referring to claim 16, Adler teaches the database comprises one-valued *or* many-valued allocations or relationships of curvature types to models related to the study of bones, and wherein the model related to the study of bones selection device is suited to select a model related to the study of bones on the basis of these allocations (Col. 7, lines 45 – Col. 8, line 7).

Referring to claim 26, Adler teaches the step of calculating comprises interpolating between different models (Fig. 2; Col. 6, lines 53-65).

Referring to claim 26, Adler teaches the patient data of which are known (Fig. 1, element 105).

Referring to claim 27, Adler teaches said step of calculating comprises determining a curvature type of the patient's bone to be selected from a predefined number of curvature types on the basis of patient's data, and selecting an model from a predefined number of models on the basis of the determined curvature type (Col. 7, lines 45 – Col. 8, line 7).

Referring to claims 1-3, 15-17, and 25-27, Adler teaches all of the limitation set forth above and further teaches the following:

“the principles disclosed here are applicable to quite general settings, medical or otherwise, we will concentrate on the study of the spine of patients afflicted with idiopathic scoliosis. Idiopathic scoliosis is a condition which affects a very large bone structure, the spine. Since X-ray analysis is commonly used in the study of bones (Magnetic Resonance Imaging (MRI) and other non-invasive techniques lack the kind of precision one needs for several purposes like the analysis of scoliosis), the size of the spine and the limited amount of X-ray that a patient can withstand forbid fine X-ray computer tomography (CT) scanning as a method to get a three dimensional representation. Furthermore, the evolutive nature of the condition implies that examinations have to be frequently repeated, with accumulative radiation hazard, which is another reason to look for small doses of radiations in the process of data acquisition.

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(8) Idiopathic scoliosis is a little understood disease. It is a progressive three dimensional (3-D) deformation of the spine involving curvature and torsion which affects about 3% of adolescents, one fifth of whom require extensive medical testing to determine whether dramatic and dangerous surgery will be required. A general reference on scoliosis can be found in Moe's Textbook of Scoliosis and Other Spinal Deformities by John E. Lonstein, David S. Bradford, Robert B. Winter and James Ogilvie, 3rd edition, W. B. Saunders & Co., 1995. Many authors have tried to explain the possible etiology of scoliosis. The term "idiopathic", means "different suffering" in Greek: "idiopathic scoliosis" has the sense of "enigmatic scoliosis".

(9) Scoliosis, in general, is a major deformity that involves practically the whole musculo-skeletal system, and probably other systems as well. Attempts to explain the phenomenon have led to some nosological successes in which a minority of patients have been diagnosed as suffering from something other than idiopathic scoliosis. For that disease, however, the mystery remains. How can a major pathological process that changes practically the whole body go unexplained, with an undetected source? This comprises probably one of the most fascinating enigmas of medicine.

(10) Severe scoliosis leads to one of the grandest surgical procedures known to medicine. The primary goal of surgery is to prevent further deterioration, the secondary one is to correct the deformity as much as is still possible. Spinal fusion is the current treatment. It has absolutely nothing to do with the basic etiology and pathophysiology of the disease and does not attempt to treat its cause. It is a crude mechanical approach which can often lead to subsequent problems. Nevertheless, until a better solution is found, it is the best option.

(11) Problems to be Solved

(12) The spine is an extremely complex object consisting of twenty-four vertebrae, which are themselves complicated objects, separated by disks. One must get a simpler geometric representation of the full spine which will capture the essential aspects of the three-dimensional information involved in idiopathic scoliosis. In the present disclosure we shall provide a mean of obtaining a wire-frame like approximation to the vertebral bodies and their relative positions from radiological data. The result will allow the practitioner to obtain all the measurements available in previous art as well as a better understanding of the three-dimensional deformation of the spine." (Col. 1, line 30- Col. 2, line 28).

While the claims, as such, do not require that the models are directed to designing a split or brace or other bodily support, and further the claims, as such, do not require making any split or brace or other bodily support from these models, Adler fails to teach the models are orthosis models.

However, Clynnch teaches analogous art (both in the background of the invention and the invention itself), wherein a system and method adapted for producing many medical devices from models such as, orthotic structures, including those applicable to a patients back (Abstract;



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Col. 7, lines 13-51), in which the manufacture of such devices from the models makes the devices more widely available to the public at less cost, and furthermore, is very effective in producing custom fitted prosthetic and orthotic devices which are comfortable to wear and provide extensive service (Col. 1, lines 5-49).

Therefore, it would have been obvious to one of ordinary skill in the art at the time that the invention was made to modify the teachings of Adler with the system and method adapted for producing many medical devices from models such as, orthotic structures, including those applicable to a patients back, as taught by Clynch.

One of ordinary skill in the art would have been motivated to combine these references because Clynch teaches a system and method adapted for producing many medical devices from models such as, orthotic structures, including those applicable to a patients back (Abstract; Col. 7, lines 13-51), in which the manufacture of such devices from the models makes the devices more widely available to the public at less cost, and furthermore, is very effective in producing custom fitted prosthetic and orthotic devices which are comfortable to wear and provide extensive service (Col. 1, lines 5-49).

### *Conclusion*

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean P. Shechtman whose telephone number is (571) 272-3754. The examiner can normally be reached on 9:30am-6:00pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo P. Picard can be reached on (571) 272-3749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SPS

Sean P. Shechtman

August 19, 2005

  
**ALBERT W. PALADINI**  
**PRIMARY EXAMINER**